DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 23, 2015

Jedmed Instrument Company
% Mr. Craig R. Parks
Regulatory Affairs/QA Manager
5416 JEDMED Court
St. Louis, Missouri 63129

Re: K150248
Trade/Device Name: ORL Video Nasopharyngo-laryngoscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EQN
Dated: February 3, 2015
Received: June 25, 2015

Dear Mr. Parks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose,
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150248

Device Name
ORL Video Nasopharyngo-Laryngoscope

Indications for Use *(Describe)*
Jedmed ORL Video Nasopharyngo-Laryngoscopes are intended to examine the larynx, nasal cavity and nasal pharynx. They are used between the upper respiratory tracts of the nasal passage and vocal cords.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

An Employee-Owned Company
5416 JEDMED COURT • ST. LOUIS, MO 63129 PHONE: (314) 845-3770 •FAX: (314) 845-3771
E-MAIL: INFO@JEDMED.COM WEB SITE: www.jedmed.com

6. 510(k) - Summary

Submitter:	JEDMED Instrument Company 5416 JEDMED Court St. Louis, MO 63129
Contact:	Craig Parks Regulatory Affairs /QA Manager Phone: 314-845-3770 Email: craigp@jedmed.com
Date:	07-21-2015
Name of Device:	ORL Video NasoPharyngo-Laryngoscope
Common Name:	Naso-pharyngo-laryngo-flexible scope
Classification Name of Device:	Laryngo, Nasopharyngoscope a) product code: EQN b) regulation number: 874.4760
Legally Marketed Device Claimed:	Flexible naso-pharyngo-laryngoscope to which Equivalence is claimed JEDMED Instrument Company K132039 ERGOFLEX NasoPharyngolaryngoscope Vision Science Flexible ENT 5000 K102733
Description:	This flexible scope is designed with the insertion tube with its bendable distal tip w/camera, the handle, the umbilical unit which has the leakage tester, and connection for light source port and power/video port The handle incorporates the control lever to bend the distal tip.
Indications for Use:	Jedmed ORL Video Nasopharyngo-Laryngoscopes are intended to examine the larynx, nasal cavity and nasal pharynx. They are used between the upper respiratory tracts of the nasal passage and vocal cords.

An Employee-Owned Company
5416 JEDMED COURT • ST. LOUIS, MO 63129 PHONE: (314) 845-3770 •FAX: (314) 845-3771
E-MAIL: INFO@JEDMED.COM WEB SITE: www.jedmed.com

6. 510(k) - Summary

Similarities/differences to predicates:

The submitted devices are equivalent to the flexible endoscopes referred to in K132039 Ergoflex NasoPharyngo-Laryngoscope .
The fiberscopes in the submission use the same basic design and device material as predicate device. This device does have an eyepiece for visualization, and can be connected to a camera system while the submitted device incorporates the camera in the tip and does not have direct visualization

The submitted devices are equivalent to the Flexible ENT 5000 scope from Vision Sciences 510(k)# 102733. Both devices use a camera system for visualization without the eyepiece. There are only differences regarding diameters and lengths of the device insertion tube and the outer appearance and shaping of the shell parts and control elements which has no bearing on the safety or effectiveness.

All the devices have the same intended use, to examine the larynx, nasal cavity and nasal pharynx. They are used between the upper respiratory tracts of the nasal passage and the vocal cords

Testing: The ORL Video Naso-Pharyngo-Laryngoscope was tested functionally and compared to the predicate device the ErgoFlex Naso-Pharyngo-Laryngoscope 510(k)# K132039 and found to be comparable. The test included Field of View, Depth of View, Angulation of the Bendable Tip, Color Output, Clarity, and Tip Diameter. Both scopes were tested with the same test fixtures and results compared by our knowledgeable field staff.
A cleaning and high-level disinfection test was also performed on the ORL Video Naso-Pharyngo-Laryngoscope for both Cidex 2.4% Activated Dialdehyde and Cidex OPA disinfectant solutions. The test dictated that a significant level of microbial reduction must result from tests for both vegetative microorganisms and mycobacteria. Based on the test criteria, the general disinfection processing employing both Cidex 2.4% Activated Dialdehyde and Cidex OPA (performed by Geneva Laboratories per the IFU) fully met the validation acceptance requirements for the Jedmed ORL Laryngo-Nasopharyngoscope.

The submitted devices pose the same type of questions about safety and effectiveness as the compared devices. The different technological characteristics have no influence on safety or effectiveness, therefore our device is substantially equivalent to the previously cleared device.

	Device under Review	**Predicate Device K132039**	**Predicate Device K102733**
Device Name	ORL Video NasoPharyngo-Laryngoscope	ERGOFLEX NasoPharyngo-Laryngoscope JEDMED Instrument	Vision Science ENT-5000
Indication for Use	Examination of the larynx, nasal cavity, nasal pharynx and is used between the upper nasal respiratory tracts and of the nasal passage and vocal chords.	Same	Same with the addition of arthroscopic and endoscopic visualization of an interior cavity of the body thru natural or surgical openings.
Viewing Method	Camera System	Same	Same
Working Length	310mm	310mm	300mm
Field of View	90º	90º	90º
Depth of View	10mm-55mm	10-55mm	3mm-50mm
Tube Diameter	4mm	4mm	3mm
Angulation	130º Up 130º Down	130º Up 130º Down	140º Up 140º Down
Video Format	NTSC---PAL/NTSC	NTSC---PAL	CCD
Resolution	320x240 500x582 510x492	320x240 & 500x582/510x492	
Product Code	EQN	EQN	EOB and HRX and GCJ
Light Guide Connector	ACMI-Wolf-Storz-Olympus	ACMI-Wolf-Storz-Olympus	ACMI-Wolf-Storz-Olympus
Direct View Eyepiece	None	None	None